

Miracle Aid, misbranding, Section 502 (a), the following statements on the package and in the catalog were false and misleading since the product would not remove wrinkles and double chin: (Catalog) "Wrinkles and Double Chin Vanish with Miracle Aid Lotion * * * you feel a gentle tightening effect on the expression wrinkles and chin line. It is very effective if left on over night"; (package label) "For Wrinkles and Double Chin * * * Apply by patting with finger tips, on wrinkles and double chin."

DISPOSITION: June 26, 1945. No claimant having appeared, judgment of condemnation was entered and the products and catalogs were ordered destroyed.

1655. Misbranding of Dismuke's Pronto-Lax, Dismuke's Famous Mineral Crystals, Famous Residuum, Dismuke's Nose Spraying Solution, and Dismuke's Eye Bath. U. S. v. 40 Bottles of Dismuke's Pronto-Lax, etc. Default decree of condemnation and destruction. (F. D. C. No. 16348. Sample Nos. 21861-H to 21865-H, incl.)

LIBEL FILED: June 23, 1945, Western District of Tennessee.

ALLEGED SHIPMENT: By the Famous Mineral Water Co., from Mineral Wells, Tex. The articles of drug were shipped on or about January 14 and April 3, 1945, and the circulars were shipped in December 1944.

PRODUCT: 40 bottles of *Dismuke's Pronto-Lax*, 6 boxes of *Dismuke's Famous Mineral Crystals*, 3 bottles of *Famous Residuum*, 4 bottles of *Dismuke's Nose Spraying Solution*, 6 bottles of *Dismuke's Eye Bath*, and 500 white circulars entitled "Dismuke's Famous Mineral Water at the sign of the Old Mill" and 10 yellow circulars entitled "The Original and Genuine Famous Mineral Crystals," at Memphis, Tenn.

Examination showed that the *Pronto-Lax* consisted essentially of water and sodium sulfate, with small proportions of salt, sodium carbonate, sodium bicarbonate, and magnesium chloride; that the *mineral crystals* consisted essentially of sodium sulfate with small proportions of salt and sodium carbonate; that the *Residuum* consisted essentially of water, salt, sodium sulfate, sodium carbonate, and sodium nitrite; that the *nose spraying solution* consisted essentially of water, salt, sodium sulfate, sodium carbonate, and sodium nitrite; and that the *eye bath* consisted essentially of water, salt, sodium sulfate, and sodium carbonate.

NATURE OF CHARGE: *Pronto-Lax*, misbranding, Section 502 (a), certain statements in the white circulars were false and misleading in that they represented and suggested that the article had been endorsed by the Food and Drug Administration; that it was a non-habit-forming laxative; that it was effective as a tonic; that it was effective to eliminate acid, waste, and toxic poisons from the system; and that it was effective in the treatment of diabetes, enlarged liver, carbuncles, stomach trouble, mucous colitis, sciatic rheumatism, constipation, stomach ulcers, and auto-intoxication. The article had not been endorsed by the Food and Drug Administration; it was a habit-forming laxative; and it was not effective for the symptoms, conditions, and diseases stated and implied. Further misbranding, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to warn that frequent and continued use might result in dependence upon laxatives.

Mineral crystals, misbranding, Section 502 (a), certain statements in the yellow circulars were false and misleading since they represented and suggested that the article would purify the system by flushing the intestinal tract; that it would often be beneficial after excessive eating or drinking; and that it would prove beneficial in treating acid stomach, colds, headaches, biliousness, indigestion, constipation, bad complexion, rheumatism, arthritis, neuritis, high blood pressure, and diabetes. The article would not be effective in the treatment of the conditions stated and implied. Further misbranding, Section 502 (a), the label statement, "Contents: Sodium Sulphate, Sodium Chloride, Magnesium Sulphate, Magnesium Carbonate, Calcium Carbonate, Iron and Aluminium Oxides," was misleading since it failed to reveal the material fact that sodium sulfate was the only active ingredient; and, Section 502 (f) (2), the article was essentially a laxative and its labeling failed to warn that frequent and continued use might result in dependence upon laxatives.

Residuum, misbranding, Section 502 (a), certain statements on the bottle label and in the white circulars were false and misleading since they represented and suggested that the article would be effective in the treatment of cuts, sores, burns, eczema, rash, poison ivy, indigestion, gastric ailments, acid

stomach, colic, and ulcerated stomach. The article would not be effective in the treatment of the conditions stated and implied.

Nose spraying solution, misbranding, Section 502 (a), certain statements on the bottle label and in the white circulars were false and misleading since they represented and suggested that the article would be effective in the treatment of head colds, hay fever, and sinus and catarrhal ailments. The article would not be effective for those purposes.

Eye bath, misbranding, Section 502 (a), certain statements in the white circulars which represented and suggested that the article would be beneficial in the treatment of eye strain, blue, granulated lids, and sore eyes were false and misleading since the article would not be effective in the treatment of the conditions stated and implied.

DISPOSITION: July 27, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1656. Misbranding of an unlabeled drug. U. S. v. 4 Unlabeled Tubes of a Certain Drug. Default decree of forfeiture and destruction. (F. D. C. No. 16148. Sample No. 17228-H.)

LABEL FILED: May 17, 1945, Southern District of Indiana.

ALLEGED SHIPMENT: On or about April 6, 1945, by the Don Curtis Keefer Laboratory, from Chicago, Ill.

PRODUCT: 4 unlabeled tubes of a certain drug at Brazil, Ind.

Analysis disclosed that the article consisted essentially of potassium soap, approximately 11.6 percent; sodium soap, approximately 11.0 percent; potassium iodide, approximately 5.7 percent; and water.

NATURE OF CHARGE: Misbranding, Section 502(b), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), it did not bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), it did not bear a label containing adequate directions for use.

DISPOSITION: June 30, 1945. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

1657. Adulteration of posterior pituitary obstetrical and Ribothiacine. U. S. v. Western Pharmacal Co. Plea of nolo contendere. Fine, \$500. (F. D. C. No. 15562. Sample Nos. 15666-F, 74279-F.)

INFORMATION FILED: July 18, 1945, Southern District of California, against the Western Pharmacal Co., Los Angeles, Calif.

ALLEGED SHIPMENT: On or about July 6 and August 4, 1944, from the State of California into the States of Arizona and Texas.

LABEL, IN PART: "Soltan Posterior Pituitary Obstetrical U. S. P. XI * * * Manufactured for Soltan Corporation Los Angeles Calif."; and "Western Ribothiacine A sterile solution."

NATURE OF CHARGE: *Posterior pituitary obstetrical*, adulteration, Section 501 (b), the article purported to be and was represented as a drug the names of which, "Solution of Posterior Pituitary U. S. P. XI" and "Posterior Pituitary Injection," are recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from, and its quality and purity fell below, the official standard since it possessed a physiological activity of not more than 22 percent of that required by the Pharmacopoeia; it contained undissolved material, which is not permitted in the official product; and its difference from the official standard was not plainly stated, or stated at all, on the label.

Ribothiacine, adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was a solution of a soluble medicament intended for injection through the skin, and therefore should have been free from undissolved material, whereas the article was contaminated with undissolved material.

DISPOSITION: August 27, 1945. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$250 was imposed on each of the 2 counts.